



MAR 31 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cindy Wang
Tianjin Medis International Trade Company, Limited
Wanshun Garden Rm. C 1801
89# Huangpu Nan Road
Hexi, 300201, Tianjin China

Re: K060082
Trade/Device Name: Tianjin Medis Disposable Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: December 30, 2005
Received: January 10, 2006

Dear Ms. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu Lin, Ph.D

Director

Division of Anesthesiology, General Hospital,


Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health.

Enclosure

	Tianjin Medis International Trade Co., Ltd.	
	Registration No: 3004992992	Owner/Operator No: 9070069

Indications for Use Statement

510(k) Number (if known): K060082

Device Name: Tianjin Medis Disposable Infusion set

Indications for Use:

Tianjin Medis Disposable Infusion set is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

☐ Part 21 CFR 801 Subpart D ☐

☐ Part 21 CFR 801 Subpart C ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Anthony D. [Signature]

[Signature] General Hosp.
Medical Devices

K060082